

The limits of legal metamorphosis – the Novel Food Status of insects

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Op-Ed: “The limits of legal metamorphosis – the Novel Food Status of insects” by Dr Sabrina Röttger-Wirtz and Dr Alie de Boer

Metamorphosis – an abrupt striking change in form, structure or substance – is generally a phenomenon witnessed in biology or common motif in prose. However, as the [Entoma case](#) shows, law also encounters this phenomenon: the novel food status of insects was subject to a potential metamorphosis under the – by now replaced – [Novel Food Regulation 258/97](#). The Court of Justice had to examine how far legal interpretation can stretch, before it amounts to completely transforming (and essentially rewriting) a legislative provision.

In 1997, very much in the [wake of the BSE crisis](#), food safety was high on the agenda in EU Law. It was also a time of radical scientific and technological advancement with the rise of nanotechnologies, cloning and genetic modification. Against this backdrop the 1997 Novel Food Regulation was adopted [to ensure](#) the safety of all foods, while only introducing a pre-market procedure for those products that were significantly changed.

What was apparently not on the table when drafting the food legislation was the consumption of insects in the average European's diet outside of TV show challenges. However, in the search for alternative protein sources and the integration of more exotic foods in European diets, insects slowly crawled on the European market. However, the Member States adopted diverging and disputed interpretations of the Novel Food Regulation, and some classified whole insects as novel foods, which made their marketing illegal before having obtained a marketing authorisation. Other Member States believed that whole insects were not considered novel under the Regulation. Ultimately, the seller of whole insects – Entoma – took legal action against a French order to withdraw its products from the market due to a lack of authorisation. This led to the *Entoma* preliminary ruling discussed here, in which the Court of Justice was asked to settle questions on whether insects are novel foods under the 1997 Regulation or not.

The Novel Food Regulation 258/97 defined novel foods on the basis of a two cumulative criteria: (i) the lack of a significant degree of human consumption of food and food ingredients in the EU before the Regulation entered into force (15 of May 1997) and (ii) if it falls into one of the six categories of foods listed in Article 1. The relevant category in question was: '(e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use'.

For context, it should be said that Novel Food Regulation 258/97 was replaced by the [new Novel Food Regulation 2015/2283](#) which was adopted due to the need to revise, clarify and update the legal framework. In the new Novel Food Regulation the fact that whole insects are covered by the novel food definition is absolutely clear, as the relevant category now reads '(v) food consisting of, isolated from, or produced from animal or their parts (...)' and Recital 8 confirms that whole insects and their parts are covered by the Regulation.

However, the Court of Justice – and the Advocate General – had to disregard the recent clarification and only examine the scope as applicable at the time. The [Opinion of AG Bobek](#) is a textbook-worthy (and highly entertaining) exercise in applying different legal interpretation methods. AG Bobek by now certainly is an expert in the judicial interpretation of EU food law in the face of changing circumstances, given that he also carried out a [similar exercise in case C-528/16](#), arguing that the new gene-editing techniques are not covered by the [GMO Deliberate Release Directive](#) (although the [Court](#) did not follow his interpretation). In *Entoma*, AG Bobek concludes that neither a

textual interpretation, nor systematic or historical interpretation would bring whole insects into the remit of the provision 'food ingredients isolated from animals'. France also argued for a teleological expansion of the scope of the regulation – based on the idea that if isolates from insects are regulated due to their risk to human health, then whole insects should be too as they present the same or an even greater risk. This dynamic interpretation of the provision in question was outright denied by AG Bobek – he called it a euphemism for legislating via '*ex post* interpretative readjustments', and made clear that an 'interpretation cannot *be contra legem*'.

In its judgment, leaning on the Opinion of the AG, the Court also engaged in a literal interpretation of the provision. It examined the usual meaning of the words and came to the conclusion that ingredients are not consumed by themselves but added substances to create food, and that 'isolated from' refers to an extraction process which excludes the whole animal from its scope. According to the Court this also holds true when examining the context and objectives of the Regulation. Thus, the Court concluded that whole insects were not covered by the 1997 Novel Food Regulation. This finding not only has historical value under the 1997 Novel Foods Regulation, but also means that whole insects can benefit from the transitional provision introduced in Article 35(2) of Regulation 2015/2283, which allows producers that marketed insects before 1 January 2018 to keep them on the market until a decision is taken on their authorisation requests that needed to be submitted until 2 January 2020.

What is the moral of this denied metamorphosis story? An often-repeated **narrative** is the EU's cautious regulation of novel products and its alleged negative effects on innovation. Nevertheless, as the case of insects shows, legal uncertainty can be equally **damaging** to an industry in the making, especially where high R&D investments are required. The costs of legal uncertainty are even more difficult to bear in an industry mostly composed of SMEs like the insects-food and feed industry. If Member States were concerned about risks to the food and feed use of whole insects, they would have had the means to address the problem without (artificially) extending the scope of the Regulation. As noted by the Court and the AG, where the Novel Food Regulation would have been deemed not to cover whole insects, the Member States had been free to adopt national measures to protect human health under the regular free movement of goods exception scheme (Articles 34 and 36 TFEU). To this we would like to add that the EU has a very detailed **food safety system** in place beyond the Novel Food Regulation, providing rules on chemical and biological safety and response mechanisms to emerging risks (like the safeguard clause in the **GFL** as well as the **RASFF**).

If some Member States were concerned about the risks of whole insects before, calling for EU harmonisation would also have been an option – as the following revision of the Novel Food Regulation has shown. So what are the potential health risks of consuming insects? In 2015, EFSA published a first **risk profile** concerning insects for food and feed use, in which it was clarified that the main safety concerns arise from microbiological hazards (due to the microbiota in the intestinal tract and on the surface of insects), chemical hazards (when the substrate on which insects are reared is contaminated), and allergenicity of insect proteins. And even though some scientific uncertainties were highlighted, five years later no new hazards have been linked to insect consumption. However, it is questionable whether there is a difference in risks from consuming whole insects or isolates from insects. In general, the microbiological and chemical hazards can be controlled by hygienic production, regardless of consumption of the whole animal or its use as a food ingredient isolated from the animal. This only changes where the consumption concerns an extract that is concentrated, as this would naturally also increase the exposure to potential hazardous substances. So scientifically speaking, the extended scope of the 2015 Novel Food Regulation is reasonable, as there is no obvious difference between the risks of whole or isolated insect foods.

However, the concerns regarding the whole insect consumption should have been explicitly addressed in unambiguous regulatory measures. Conversely, by strictly (over-)interpreting the scope instead of actually taking regulatory measures on a national or EU-level, time was lost on the road to alternative proteins. The 2015 EFSA Opinion stipulates that a lack of information on how the animals will be farmed and which forms of preparation and consumption will be proposed significantly influence the risks. Often the concrete scientific requirements for authorising a food can only be shaped with actual authorisation applications reaching the EFSA. Had the legal status been clarified earlier, then the application of the industry might have already clarified some of these data gaps. It should also be mentioned that the industry is not opposed to regulation: the relevant industry association IPFF actually provides recommendations on hygiene rules and **welcomed the 2015 Novel Food Regulation** as providing harmonised rules. Currently it is crunch time for insect regulation, as the first EFSA Opinions on submitted Novel Foods applications are anticipated to be released soon, this will also shed more light on the potential different risk profiles of insect products depending on species and forms of consumption.

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